

Updated Simplified Disease Classification Codes

CTEP will be updating IT applications (i.e., CDUS, AdEERS) Enterprise data systems on July 1, 2006 to MedDRA v9.0. The July 2006 update affects CTEP's lists of values for CTCv2.0; CTCAEv3.0, SDCv1.0., Legacy Disease Codes, Prior Therapy Codes and Pre-Existing Condition Codes.

As a result of CTEP's collaboration with caBIG, the Cancer Centers, the FDA, the MedDRA MSSO (Maintenance Service and Support Organization), and in compliance with the 2005 ICH Guidance on Data Transfer, we will be replacing Preferred Terms (PT) with Lowest Level Terms (LLT). **Note:** Because all PT codes also exist as identical LLT codes, the current PT code will be unchanged when represented as the LLT.

All local systems must be updated to utilize these new codes. As of the July 1, 2006 CTEP will no longer accept the old codes. CDUS data submissions, with the Due Date of July 31, 2006, must submit these new codes.

Simplified Disease Classification Changes:

CTEP reviewed Simplified Diseases currently associated with MedDRA v6.0 codes and updated to appropriate MedDRA v9.0 codes. As a result of these updates the percentage of Diseases with CTEP provisional codes (Starting with '9') has decreased from 32% to 7%. There were no changes to the disease terms themselves. The only change is their associated MedDRA Code.

Files Available from CTEP Website:

Text (.txt) file The text file is a comma delimited file that includes the current list of Simplified Disease Codes (Category, Sub-Category, CTEP Term, Short Name, and MedDRA codes). It can be used for importing the diseases and codes directly into local databases.

Excel (.xls) file The Excel file includes the current list of Simplified Disease Codes (Category, Sub-Category, CTEP Term, Short Name, and MedDRA codes).

Mapping Version Excel (.xls) file This Excel file includes three worksheets. One worksheet labeled "SDCv1_M9M6" includes all of the SDC terms with their MedDRA 6.0 and MedDRA 9.0 Codes along with a column to identify which diseases have updated codes. The second worksheet labeled "UpdatedCodesOnly" uses the same format but only includes diseases that have a changed code. The third worksheet labeled "Legacy_to_SDC" is a list of all of the Legacy Diseases with their legacy MedDRA codes and their corresponding SDC Disease with its MedDRA 9.0 Code.